

**REMARKS**

Entry of the foregoing, reexamination and further and favorable reconsideration of the subject application in light of the following remarks, pursuant to and consistent with 37 C.F.R. § 1.112, are respectfully requested.

By the present amendment, claims 7-14, 16 and 19-20 have been canceled without prejudice or disclaimer to the subject matter recited therein. Further, claims 2-6, 15 and 17-18 have been amended and new claims 21-27 have been added. Claims 2-6, 15 and 17-18 have been amended to include begin with an article. Claims 4, 5 and 15 have been further amended so as to be in independent form, including all of the elements of claim 21 (which replaces claim 20) or claim 26 (which replaces claim 11). The dependency of claims 2-3, 6 and 17-18 have therefore been amended appropriately. Various other minor amendments have been made to claims 2, 4, 6, 15, 17 and 18 so as to clarify applicant's invention. Support for such minor amendments can be found throughout the originally filed application. Support for new claims 21-27 can also be found throughout the originally filed application, including the specification and the claims. Hence no new matter has been added. Finally, none of the amendments to the claims, or the addition of new claims which may replace certain of the previously pending claims, have been made with the intention of limiting such claim or any element(s) recited therein.

Claims 2-6 and 15, 17-18 and 21-27 are, therefore, currently pending in the present application.

## I. REJECTIONS UNDER 35 U.S.C. § 112

### A. Rejection under 35 U.S.C. § 112, first paragraph

Claims 5 and 20 have been rejected under 35 U.S.C. §112, first paragraph for allegedly failing to comply with the written description requirement. Specifically, the Examiner has indicated that the specification does not use the phrase "a substantial amount." This rejection is respectfully traversed.

Initially, it is noted that claim 20 has been canceled without prejudice or disclaimer and thus part of the rejection is now rendered moot. However, in addition to claim 5, amended claims 4 and 6 and new claims 21 and 23 recite the phrase "removing a substantial amount of hydrogen peroxide . . ."

The specification need not describe the claimed invention *in ipsis verbis* to comply with the written description requirement. *See, e.g., Ex Parte Sorenson*, 3 U.S.P.Q.2d 1462, 1463 (PTO Bd. App. & Int. 1987). Rather, the test for determining whether the specification provides an adequate written description of the claimed invention is whether the disclosure of the originally filed application reasonably conveys to a person of ordinary skill that the inventors had possession of the subject matter claimed. *Id.*; *see also Vas-Cath, Inc. v. Mahurkar*, 19 U.S.P.Q.2d 1111, 1117 (Fed. Cir. 1991). Precisely how close the original description must come to comply with the description requirement of § 112 must be determined on a case by case basis. *See, e.g., In re Wilder*, 222 U.S.P.Q. 369, 372 (Fed. Cir. 1984). Here, recitation of removing "a substantial amount" of hydrogen peroxide is supported by the original disclosure so as to convey with reasonable clarity to

those of skill in the art that the inventor of the present application was in possession of the claimed subject matter.

While the phrase "a substantial amount" may not be identically present in applicant's originally-filed application, the word "substantial" is a relative term or a word of degree denoting a desired amount. *See Ex Parte George*, 230 U.S.P.Q. 575, 577 (PTO Bd. App. & Int. 1984). The relative amount of hydrogen peroxide which the disclosure indicates to be removed is such that a trace or residual quantity is retained. This is described at page 7, lines 3-9, of the specification where it is stated that the invention provides for "removing the hydrogen peroxide from the surface of the packaging material while retaining a residual or trace quantity at any microorganisms, . . . and residual quantity of hydrogen peroxide [being (sic)] absorbed by or located adjacent to any microorganisms present on the packaging sheet material . . . ." The removing step is further described at page 9, lines 29-30 where it is stated that ". . . reducing the hydrogen peroxide on the surface of the packaging material to a minimum" and at page 11, lines 13-7, where it is stated that "although excess hydrogen peroxide is removed from the hydrophobic packaging sheet material, a residual or trace quantity is retained at any microorganism . . . , which are believed to hydrophilically absorb the hydrogen peroxide . . . or otherwise retain the residual hydrogen peroxide."

When the packaging material emerges from, for instance, the hydrogen peroxide containing bath, a layer of hydrogen peroxide remains on the surface of the packaging material. If hydrogen peroxide is present on the surface of the packaging material when

the UV light is applied, it will shield the microorganisms from the UV light and as a result the UV light would be less effective in killing the microorganisms on the surface of the packaging material. Accordingly, when the shielding layer is removed in accordance with applicant's process, the UV radiation is applied directly to the microorganism, and since hydrogen peroxide is present in or adjacent to the microorganism, the synergism of UV light and hydrogen peroxide is achieved.

It is submitted that the steps of applicant's method, in particular removing "a substantial amount" of hydrogen peroxide are sufficiently described in the specification to reasonably convey to those skilled in the art that the inventor had possession of the claimed invention. Therefore, withdrawal of this written description rejection is respectfully requested.

B. Rejection under 35 U.S.C. § 112, second paragraph

Claims 5 and 20 have been rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for allegedly failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. More specifically, the Examiner has objected to the use of the phrase "a substantial amount of hydrogen peroxide." This rejection is respectfully traversed.

As discussed above, claim 20 has been canceled. However, claim 5, in addition to a number of other claims, still use the phrase "a substantial amount of hydrogen peroxide."

It is well established that claims are not to be read in a vacuum, and limitations therein are to be interpreted in light of the specification. *See, e.g., In re Marosi*, 218

U.S.P.Q. 289, 292 (Fed. Cir. 1983). A claim is not fatally indefinite simply because it uses a word of degree or relativity. In the present case, as described above, the amount of hydrogen peroxide which is removed is an amount so as to retain a residual or trace quantity of hydrogen peroxide absorbed by or located adjacent to any microorganisms present on the packaging material. Thus, when read in light of the specification, one of ordinary skill in the art would understand the metes and bounds of the recited claim language. As such, recitation of removing "a substantial amount" of hydrogen peroxide is not indefinite.

Accordingly, withdrawal of the Examiner's indefiniteness rejection is respectfully requested.

## **II. REJECTION UNDER 35 U.S.C. § 102(e)**

The Examiner has indicated that the changes made to 35 U.S.C. § 102(e) by the AIPA do not apply to examination of this application as the application was not filed on or after November 29, 2000 or voluntary published under 35 U.S.C. § 122(b). However, in accordance with the revisions to 35 U.S.C. § 102(e) by the Intellectual Property and High Technology Technical Amendments Act of 2002 (Pub. L. 107-273, 116 Stat. 1758 (2002)), the filing date of the present application is no longer relevant in determining what version of 35 U.S.C. § 102(e) to apply in determining the patentability of the present application. Thus, the present application should be examined under 35 U.S.C. § 102(e) as revised by the Technical Amendments Act.

Claims 2-3, 7-13, 17-18 and 20 have been rejected under 35 U.S.C. § 102(e) as purportedly being anticipated by *Swank et al.*, (U.S. Patent No. 6,039,922). This rejection is respectfully traversed.

The rejection is rendered moot with respect to claims 7-13 and 20 which have been canceled without prejudice or disclaimer to the subject matter recited therein.

To anticipate a claim under § 102, a prior art reference must show each and every element claimed; short of this, anticipation does not exist. *See, e.g., Motorola, Inc. v. Interdigital Tech., Corp.*, 43 U.S.P.Q.2d 1481, 1490 (Fed. Cir. 1997).

In rejecting claim 20 (now replaced by claim 21), the Examiner has taken the position that *Swank et al.* discloses a method for applying hydrogen peroxide to a packaging sheet material; removing a substantial amount of the hydrogen peroxide while retaining a residual amount, this residual amount being inherently absorbed by or located at microorganisms present on the packaging sheet material; and then irradiating the packaging sheet material with UV light. Contrary to the Examiner's assertion, *Swank et al.* fails to teach, explicitly and/or inherently, the claimed method and apparatus.

The sterilization process as disclosed by *Swank et al.* is fundamentally different from the claimed invention. Nonetheless, in a very general sense, *Swank et al.* discloses a non-necessary step of drying the carton after it is subjected to vapor-phase hydrogen peroxide and before entering the next substation which involves UV radiation. There is no mention, however, of how much hydrogen peroxide is removed and/or retained in the process disclosed by *Swank et al.* The Examiner has acknowledged this deficiency in the

*Swank et al.* disclosure but argues that the hot air distributor which *Swank et al.* describes for drying the coated carton is inherently capable of removing a substantial amount of the hydrogen peroxide while retaining a residual amount. Even if the Examiner's argument was not predicated on the impermissible mere conjecture as to the characteristics of the *Swank et al.* hot air distributor,<sup>1</sup> there is no explicit or inherent teaching that the microorganisms present on the surface of the packaging material absorb (or retain in or adjacent to) hydrogen peroxide.

The important discovery made by applicant is that, even though hydrogen peroxide is removed from the packaging sheet material, a residual or trace quantity of the hydrogen peroxide is absorbed or otherwise retained or adjacent to any microorganisms that are present on the packaging sheet material. This residual or trace quantity of hydrogen peroxide which is absorbed by or otherwise retained in or near the microorganisms is thus available to react synergistically with the UV light to render the microorganisms non-viable and/or sterilize the material.

The Examiner similarly argues that the absorption of hydrogen peroxide by the microorganisms is similarly an inherent result. However, inherency may not be established by probabilities or possibilities. The mere fact that a certain thing may result from a given set of circumstances is not sufficient. *See Ex Parte Skinner*. 2 U.S.P.Q. 2d 1788, 1789 (PTO Bd. Appl & Int. 1987). The initial burden of establishing a *prima facie*

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<sup>1</sup> Anticipation cannot be predicated on mere conjecture as to the characteristics of a prior art product. *See Ex Parte Standisk*, 10 U.S.P.Q. 2d 1454, 1457 (PTO Bd. App. & Int. 1989).

basis to deny patentability to a claimed invention rests upon the Examiner. The Examiner must provide a basis in fact and/or technical reasoning to reasonably support the determination that the allegedly inherent characteristic necessarily flows from the teachings of the applied art. The Examiner has not satisfied this burden. Moreover, it was known at the time of applicant's invention, that microorganism spores had low permeability to hydrophilic compounds such as hydrogen peroxide. *See, e.g.,* Irina Bagyan et al., "The *katX* Gene, Which Codes for the Catalase in Spores of *Bacillus Subtilis*, Is a Forespore-Specific Gene Controlled by  $\sigma^F$ , and *KatX* Is Essential for the Hydrogen Peroxide Resistance of the Germinating Spore," 180 J. BACTERIOLOGY, 2057-62, 2057 (1998) ("Factors contributing to increased spore hydrogen peroxide resistance include the low permeability of spores to hydrophilic compounds [citing reference from 1972] . . . ."). Thus, the facts do not reasonably support the Examiner's determination that hydrogen peroxide is absorbed by microorganisms such that, after removing a substantial amount of hydrogen peroxide from the surface of the packaging sheet material and upon irradiating the packaging sheet material with UV light, the interaction between the hydrogen peroxide and UV light still causes a killing effect on microorganisms. The killing effect caused by the invention of the present application is targeted. *See* page 11, lines 17-22, of applicant's specification. Moreover, the removal of the shielding layer of excess hydrogen peroxide allows, if desired, the advantage of using concentrations of hydrogen peroxide which are higher than the maximum levels thought to be utilizable by the prior art. *See* page 11, lines 22-25, of applicant's specification.

In view of the above, *Swank et al* fails to explicitly teach each and every element of the claims and the Examiner has failed to satisfy the requisite burden with regard to establishing inherency of those elements of the claimed invention which are not taught by *Swank et al.* Therefore, the Examiner is respectfully requested to withdraw the rejection under 35 U.S.C. § 102(e) over *Swank et al.*.

**III. REJECTIONS UNDER 35 U.S.C. § 103(a) UTILIZING SWANK ET AL. AS THE PRIMARY REFERENCE**

Claims 4 and 14 have been rejected under 35 U.S.C. § 103(a) as purportedly being unpatentable over *Swank et al.* in view of *Lolinger et al.* (U.S. Patent No. 3,692,468).

Claims 5 and 16 have been rejected under 35 U.S.C. § 103(a) as purportedly being unpatentable over *Swank et al.* in view of *Posey et al.* (U.S. Patent No. 4,783,947).

Claims 6 and 19 have been rejected under 35 U.S.C. § 103(a) as purportedly being unpatentable over *Swank et al.* in view of *Sizer et al.* (U.S. Patent No. 5,843,374)

Finally, claim 15 has been rejected under 35 U.S.C. § 103(a) as purportedly being unpatentable over *Swank et al.* in view of *Lothman et al.* (U.S. Patent No. 4,225,556).

All of four of these rejections under 35 U.S.C. § 103(a), which utilize *Swank et al.* as the primary reference, are respectfully traversed.

35 U.S.C. § 103(c) was amended to state that subject matter which was prior art under former 35 U.S.C. § 103 via 35 U.S.C. § 102(e) is now disqualified as prior art against the claimed invention if that subject matter and the claimed invention "were, at the time the invention was made, owned by the same person or subject to an obligation of

assignment to the same person." This change to 35 U.S.C. § 103(c) applies to all utility application filed on or after November 29, 1999. Since the present application was filed on April 28, 2000, the above-noted change to 35 U.S.C. § 103(c) applies to this application.

**Statement Concerning Common Ownership**

The present application — U.S. Application No. 09/530,361 — and U.S. Patent No. 6,039,922 issued to *Swank et al.* were, at the time the invention of the present application was made, owned by Tetra Laval Holdings & Finance, SA or subject to an obligation of assignment to Tetra Laval Holdings & Finance, SA.

Pursuant to section 706.02(l)(3) of the M.P.E.P., this statement concerning common ownership alone is sufficient evidence to disqualify the *Swank et al.* patent from being used in a rejection under 35 U.S.C. § 103(a) against the claims of the present application. Nonetheless, applicants note the following objective evidence of common ownership:

(1) An assignment was filed in connection with U.S. Patent No. 6,039,922 issued to *Swank et al.*, which assignment assignees the entire, right, title and interest to Assignee Tetra Laval Holdings & Finance, SA. This assignment was recorded in the U.S. Patent and Trademark Office on August 15, 1997 at Reel 8791, Frame 0154.

(2) An assignment was filed in connection with the present application — U.S. Application No. 09/530,361 —, which assignment assignees the entire, right, title and interest to Assignee Tetra Laval Holdings & Finance, SA. This assignment was recorded in the U.S. Patent and Trademark Office on April 28, 2000 at Reel 010823, Frame 0465.

In view of the above, *Swank et al.* is disqualified as prior art in the Examiner's rejections under 35 U.S.C. § 103(a). Moreover, none of the secondary references (*Lolinger et al.*, *Posey et al.*, *Sizer et al.*, or *Lothman et al.*) teach or suggest the claimed invention. It is also noted that part of three of the rejections are rendered moot since claims 14, 16 and 19 have been canceled without prejudice or disclaimer to the subject matter recited therein.

Accordingly, withdrawal of all four rejections under 35 U.S.C. § 103(a) is respectfully requested.

#### IV. CONCLUSION

In view of the foregoing, further and favorable action in the form of a Notice of Allowance is believed to be next in order. Such action is earnestly solicited.

In the event that there are any questions relating to this application, it would be appreciated if the Examiner would telephone the undersigned attorney concerning such questions so that prosecution of this application may be expedited.

Respectfully submitted,

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